REMARKS

Claims 1-3 and 6-7 currently appear in this application. The Office Action of April 9, 2003, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Art Rejections

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Konno et al. and Fujishima et al.

This rejection is respectfully traversed. The claims have now been amended so that R^1 represents only 4-hydroxy-4-methylpentyl, and R^2 only represents hydroxymethyl, hydroxyethyl, hydroxypropyl, ethyl, or butyl. Neither of these cited references anticipates the amended claims.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Posner et al.

This rejection is respectfully traversed. The claims have now been amended so that R^1 represents only 4-hydroxy-4-methylpentyl, and R^2 only represents hydroxymethyl, hydroxyethyl, hydroxypropyl, ethyl, or

butyl. There is nothing in Posner et al. that teaches or suggests these particular compounds.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konno et al. and Fujishima et al.

This rejection is respectfully traversed. As the Examiner pointed out on page 7 of the outstanding Office Action, there is a general lack of predictability in the pharmaceutical art, and even a minor change in the position of a stereo isomer can change the activity of a compound. Therefore, if a group of compounds having 2-α substitutions (2-α compounds) are reported to be superior to their corresponding 2-β compounds, one cannot reasonably expect that **other** groups of 2-α compounds will be superior to their corresponding 2-β compounds.

According to Tsugawa et al., *Biol. Pham. Bull.* **23(1)**, 66-71, 2000, a copy of which was filed with Dr. Takayama's declaration, the VDR binding property of the 2b-propyl compound AK-3 is 25% (Table 3, page 70), which is **greater** than that of the 2-α-propyl compound (20%), indicated as compound 35 on page 51 of the specification of the instant application. Therefore, it is respectfully submitted that one skilled in the art cannot reasonably expect that all 2-α compounds will be superior to their corresponding 2-β compounds.

Rejections under 35 U.S.C. 112

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is respectfully traversed. Claims 8-15, which clam a therapeutic agent for a disease associated with abnormal calcium metabolism, have been cancelled from the present application.

As the Examiner is well aware, derivatives of a compound are compounds based upon the original compound. Generally, the term "derivatives", unless otherwise defined is considered to be vague and indefinite. However, as the Examiner can appreciate, when the "derivatives" are limited to specific compounds defined by a formula, there can be no question of indefiniteness.

Nonetheless, since the Examiner appears to have difficulty appreciating that the compounds claimed are specific compounds and not "derivatives" in general, the claims have been amended to recite --vitamin D compound-- The scope of the claims has not been changed by this amendment, only the word used to describe the compounds of the formulae given in the claims.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was

not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is respectfully traversed. The claims have been limited to specific compounds disclosed in the specification.

Double Patenting

Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of application Serial No. 09/214,155 and claims 1-3, 5-8 and 10-13 of Serial No. 09/959,541, respectively.

Applicant's attorney does not have access to Serial No. 09/214,155, but assumes that the amendments to the claims have overcome the double patenting rejection. With respect to Serial No. 09/959,541, it is respectfully submitted that the amendments to the claims now obviate a double patenting rejection.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly

solicited.

Respectfully submitted,

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